DOCKET NO.: 133087.07501 (100711-1P US) **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Roth-Rosendahl and Svernhage**

Serial No.: **10/516,426** Group Art Unit: **4133**

Filed: **June 28, 2005** Examiner: **Darryl C. Sutton**

Title: **Pharmaceutical Combination**

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

RESPONSE TO THE RESTRICTION REQUIREMENT

The present Response is filed in regard to the Restriction Requirement mailed October 31, 2007 in regard to the above-identified patent application. The period for responding to the Restriction Requirement has been extended, by enclosure of a petition and fee, to and through January 31, 2008.

The Office has restricted the claims into the following Groups: Group I (claims 1 and 3, 5, 6, 11) drawn to "a combination product comprising an admixture of compounds;" Group II (claims 2, 6, 10) drawn to "a combination which can include a compound of claim 20;" Group III (claims 4, 6 and 8) drawn to "kits comprised of a) anti-coagulation compounds or their derivatives and b) anti-arrhythmia compounds or their derivatives;" Group IV (claim 7) drawn to "the method of making a kit comprised of anti-coagulation compounds and anti-arrhythmia compounds;" and Group V (claim 9) drawn to "the method of treating arrhythmia." **Applicants elect Group I (claims 1 and 3, 5, 6, 11) drawn to "a combination product comprising an admixture of compounds" with traverse.**

As a preliminary matter, Article 27(1) PCT does not allow any national law to require compliance with requirements relating to the content of an international application different from or additional to those provided for in the PCT. Significantly, a unity of invention objection

was not raised during the international phase of the application. Thus, it is not considered appropriate that such an objection be raised during the national phase. The Office is also reminded that PCT Applicants Guide, Volume 1 paragraph 138 states that "an international application which complies with the unity of invention requirements laid down in rule 13 must be accepted by all the designated and elected offices…" Accordingly, since there was no unity of invention objection raised during the international phase, Applicants submit that such an objection should not and cannot be raised now.

Notwithstanding the aforementioned position, the Office's reasoning for the unity of invention objection is flawed. The only reasoning provided for the restriction between the five groups is the assertion that the compounds of the composition in Group I "are formulated in an admixture" whereas the compounds of the composition in Group III have "a limitation where the compounds would be administered separately." This reasoning in insufficient and does not support restriction between the five groups.

First, no reason whatsoever is provided by the Office for restricting the claims of Group I apart from the claims of Group II. Claim 1 (in Group I) recites a combination product of (a) and (b), wherein each of (a) and (b) is formulated in admixture with a pharmaceutically-acceptable adjuvant, diluent or carrier. Claim 2 (in Group II) is dependent upon claim 1 and recites that the combination product of claim 1 is present within a pharmaceutical formulation. Indeed, the particular compounds within the combination product of claim 2 are within the scope of the combination product of claim 1. Thus, one general inventive concept shared by claim 1 and claim 2, for example, is the combination product of compounds of (a) and (b). Thus, there is no need or basis for restricting claim 1 from claim 2, or any of the claims of Group I from the claims of Group II. Nor does the Office even provide sufficient reasoning for such restriction.

The claims of Group III also recite the combination product, which, as stated above, is one general inventive concept shared by Groups I-III. Thus, at the very minimum, Groups I, II, and III should be combined into a single group.

The Office also asserts that claims 1-11 are generic and that the application contains claims directed to more than one species of the generic invention. The species indicated by the Office are species (a) compounds of claim 1 or of claim 20 of WO 02/44145 and (b) compounds

of claim 1 or claim 34 of WO 01/28992 or Compounds A, B, C, or D. One reason for the election of species provided by the Office is that "the species (a and b) have different structures and are used to treat distinct patient populations that do not overlap" (see page 3-4). Applicants submit, however, that a species election between the compounds of (a) and (b) cannot be issued. The Office is reminded that the claims recite a "combination product" which comprises a compound from (a) and a compound from (b) – hence, a combination product. That the compounds of (a) and (b) have different structures and are used to treat distinct patient populations that do not overlap is not a sufficient reason for a species election and, most importantly, destroys the claims. Applicants are unable to select either (a) or (b) species – such selection would, in fact, eliminate the combination product. For the sake of completeness, however, Applicants understand that a species must be elected – Applicants elect species (a), with traverse for the reasons previously discussed.

Applicants submit that the present response is complete and complies with the requirements of 35 U.S.C. §121.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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Date: **25 January 2008**

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